

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
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THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9071

Bartle, J.

May 22, 2013

The Estate of Ronald J. Bonzo ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Barbara Bonzo, Ronald J. Bonzo's ("Mr. Bonzo" or "decedent") spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the

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To seek Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In August, 2003, Faydra Hope, Representative of Mr. Bonzo's estate, submitted a completed Green Form to the Trust signed by decedent's attesting physician, Arthur Levene, M.D. Based on an echocardiogram dated December 19, 1997, Dr. Levene attested in Part II of the Green Form that Mr. Bonzo suffered

3. (...continued)
severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to representative claimants where Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

from moderate mitral regurgitation, mild aortic regurgitation, a reduced ejection fraction in the range of 50% to 60%, death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery, and ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise. Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$1,378,155.⁵

In the report of Mr. Bonzo's echocardiogram, the reviewing cardiologist, Roger Fellows, M.D., observed that

5. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient: (1) suffered death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use as supported by a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and medical records; or (2) "otherwise qualifies for payment at Matrix Level II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." See Settlement Agreement §§ IV.B.2.c.(5)(c)-(d). A representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b). The Trust did not contest that Mr. Bonzo suffered from mild aortic regurgitation; a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim; or ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise. Thus, the Estate is entitled to Level V benefits if Mr. Bonzo had at least moderate mitral regurgitation or if he died as a result of a condition caused by valvular heart disease or valvular repair/replacement surgery that occurred post-Pondimin® and/or Redux™ use supported by a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records.

Mr. Bonzo had "[t]ransient mitral regurgitation."⁶ Dr. Fellows, however, did not specify a percentage as to the level of decedent's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2006, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists.⁷ In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Levene's finding that the decedent had moderate mitral regurgitation. Specifically, Dr. Irani stated that the "[e]cho report states trace [mitral regurgitation]."⁸ In addition, Dr. Irani concluded that there was no reasonable medical basis for Dr. Levene's finding that

6. Dr. Fellows also determined that decedent's echocardiogram demonstrated "transient to mild aortic insufficiency."

7. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level V claim, the Trust audited the Estate's claim pursuant to the PPP.

8. Dr. Irani relied on the report of Mr. Bonzo's December 19, 1997 echocardiogram because claimant did not provide the Trust with a copy of the echocardiogram tape. Pursuant to Section VI.C.2.e. of the Settlement Agreement, claimant submitted an affidavit by Dr. Levene wherein he stated that, despite having the original echocardiogram tape in his possession at the time he completed the Green Form, he has since been unable to locate it. Dr. Levene also stated that he reviewed the original echocardiogram tape and concluded that it demonstrated that Mr. Bonzo suffered from moderate mitral regurgitation.

Mr. Bonzo's death resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery. Dr. Irani explained, "Unable to accurately answer. Given Echo report dated 12/19/97 [patient] did not have significant valvular heart disease. Out of hospital sudden death causes may include arrhythmia - both tachycardia or bradycardia."

Based on the auditing cardiologist's findings and the Estate's failure to submit a statement from Mr. Bonzo's attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁹ In contest, the Estate argued that it did not submit "a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist" because there was no Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist attending to Mr. Bonzo at the time of his sudden death. The Estate also asserted that its claim could not be denied simply because the echocardiogram on which the claim is based is missing since the Estate submitted an affidavit of the person who last had custody of the

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

echocardiogram tape as required by the Settlement Agreement. See Settlement Agreement §§ VI.C.2.e.-f.

In addition, the Estate contended that there was a reasonable medical basis for Dr. Levene's representation that Mr. Bonzo had moderate mitral regurgitation. In support, the Estate submitted an affidavit from Dr. Levene wherein he stated, in pertinent part, that:

Based upon my personal review of the original echocardiogram tape of the echocardiogram performed on Ronald J. Bonzo on December 19, 1997, I determined that Ronald Bonzo had moderate mitral regurgitation, defined as regurgitant jet area in any apical view equal to or greater than 20% of the left atrial area but less than or equal to 40% (20% to 40% RJA/LAA).

The Estate also submitted a letter from Dr. Levene dated May 15, 2006, wherein he stated, in pertinent part, that:

[T]he report [of Mr. Bonzo's echocardiogram] is very vague, talking about transient regurgitation, which is a bizarre term. I am not sure how that term was used. The auditing cardiologist obviously could not review the echocardiogram itself. I previously viewed the echocardiogram of Mr. Bonzo on March 21, 2000. Since that time it has gone missing. At that time we determined [decedent] had evidence of mitral regurgitation with a jet area of greater than 20% to left atrial size.... I do understand where the auditing cardiologist is coming from in his report, but he is only basing it on the report of the echocardiogram from December 19, 1997, having never reviewed the tape himself. I was fortunate to have reviewed that tape and made my determination based on that. The progression and the autopsy confirm that my diagnosis was more likely correct.

The Estate asserted that Dr. Levene's conclusion that Mr. Bonzo had moderate mitral regurgitation was corroborated by decedent's Autopsy Report, which specifically concluded that one of the causes of the decedent's death was "[m]itral valve insufficiency" and that decedent's "mitral valve appears abnormal with one leaf elongated."

The Trust then issued a final post-audit determination, again denying the Estate's claim. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On September 1, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6538 (Sept. 1, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on December 21, 2006, and the Estate submitted a sur-reply on February 2, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for the attesting physician's findings

that Mr. Bonzo died as a result of a condition caused by VHD or that Mr. Bonzo suffered from moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in the Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate raises the arguments it raised in contest, namely, that there is a reasonable medical basis for Dr. Levene's representation that Mr. Bonzo had moderate mitral regurgitation and that it is not required to submit a statement of an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist because Mr. Bonzo did not have an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist at the time of his death. In addition, the Estate maintains that Dr. Irani's responses at audit should be stricken and disregarded because Dr. Irani did not comply with the Audit Rules. According to the Estate, Audit Rule 7(a) required the auditing cardiologist to answer that the echocardiogram on which the Green Form responses were based was "Not Evaluable" and, as a result, Audit Rule 7(c) precluded Dr. Irani from offering an opinion as to the reasonableness of Dr. Levene's representations. Moreover, the

Estate argues that the Trust and Dr. Irani violated Audit Rule 23(b) because the Statement of the Case and Dr. Irani's certification implies that Dr. Irani reviewed the echocardiogram tape and made findings based on his review.

In response, the Trust argues that the Estate is not entitled to Level V benefits because there is no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation and the Estate did not provide a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist stating that the decedent's death resulted from a condition caused by VHD. The Trust also asserts that the Estate misinterprets the Settlement Agreement and Audit Rules with regard to the auditing cardiologist's review. Specifically, the Trust contends that the Section VI.C.4.b. of the Settlement Agreement authorizes the auditing cardiologist to consider other medical records to determine whether there is a reasonable medical basis for Green Form representations based on a missing echocardiogram. Finally, the Trust submits that the auditing cardiologist conducted the audit in accordance with the Settlement Agreement and the Audit Rules.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As an initial matter, we reject the Estate's argument that it is not required to provide a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist. The Estate does not dispute that it has not submitted such a

statement. Instead, the Estate argues that it should not be required to submit such a statement because Mr. Bonzo did not have an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist at the time of his death. We disagree. The Settlement Agreement specifically provides that an eligible representative claimant is entitled to Level V benefits if the Diet Drug Recipient suffered:

Death resulting from a condition caused by
valvular heart disease or valvular
repair/replacement surgery which occurred
post-Pondimin® and/or Redux™ use supported by
a statement from the attending
Board-Certified Cardiothoracic Surgeon or
Board-Certified Cardiologist, supported by
medical records.

See Settlement Agreement § IV.B.2.c.(5)(c). The Estate essentially argues that it should not be required to comply with this portion of the Settlement Agreement. We, however, must apply the Settlement Agreement as written. Accordingly, the Estate is not entitled to receive benefits under this section of the Settlement Agreement.¹⁰

We also find that the Estate has not established that it is eligible to receive Matrix Benefits based on damage to decedent's mitral valve. The Settlement Agreement states that a representative claimant is eligible for Matrix Benefits only if the Diet Drug Recipient "ha[s] been diagnosed by a Qualified

10. Given our disposition, we need not determine whether Mr. Bonzo actually died as a result of a condition caused by VHD.

Physician as FDA Positive¹¹ or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period." Settlement Agreement § IV.B.1.b. Thus, the Estate must establish that decedent had at least mild mitral regurgitation to be eligible to seek Matrix Benefits for damage to his or her mitral valve.¹²

As an initial matter, the Estate's argument that the Trust improperly relied on the echocardiogram report rather than the findings set forth in the affidavit of Dr. Levene is misplaced. Although the Estate correctly notes that the Settlement Agreement permits a claimant or representative claimant to supply an affidavit from the person who last had custody of an echocardiogram tape or disk if the echocardiogram tape or disk is no longer in existence, nothing in the Settlement Agreement or Audit Rules suggests that such affidavit conclusively establishes the Green Form representation at issue

11. The Settlement Agreement defines FDA Positive, in pertinent part, as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." Settlement Agreement § I.22.

12. The Estate's claim for Level V benefits is based on Section IV.B.2.c.(5)(d), which requires a decedent to "otherwise qualif[y] for payment at Matrix Level II, III or IV" and to have "suffer[ed] from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." The Estate's claim for Level V benefits is based solely on damage to decedent's mitral valve. Thus, to recover Matrix Benefits under this section, the Estate must establish that the December 19, 1997 echocardiogram demonstrated moderate mitral regurgitation.

or that an auditing cardiologist is precluded from considering other information.

Pursuant to Section VI.C.4.b. of the Settlement Agreement, in the case of a missing echocardiogram tape or disk, the Trust has the right to consider other documents submitted in support of a claim. Specifically, Section VI.C.4.b. provides:

If the Class Member seeking a Matrix payment is unable to obtain the documentation described above through the exercise of reasonable efforts, the Trustees and/or Claims Administrator(s) shall have the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty to support the claim that the Class Member's condition entitles him or her to a Matrix payment, subject to review by the Court as set forth in Section VIII.D. If this evidence establishes the Class Member's condition to the satisfaction of the Trustees and/or Claims Administrator(s), the Class Member shall be entitled to receive the appropriate Matrix Compensation Benefits.

The Trust reviewed the documents submitted by the Estate in support of its claim and determined that there was no reasonable basis for the attesting physician's conclusion that the December 19, 1997 echocardiogram demonstrated moderate mitral regurgitation.¹³ We agree. Neither the Estate nor the attesting

13. We reject claimant's argument that an auditing cardiologist is not permitted, in the case of a missing echocardiogram, to review other supporting documentation, including an echocardiogram report and other medical records submitted by a claimant, to determine whether a reasonable medical basis exists for the attesting physician's representations. In any event, we find that the Trust's decision to deny the Estate's claim was

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physician, Dr. Levene, identified any medical record or supporting documentation contemporaneous with the echocardiogram that would support a finding of either mild or moderate mitral regurgitation. Instead, the Estate relies on Dr. Levene's statement that he reviewed the actual echocardiogram and determined it demonstrated moderate mitral regurgitation and that the term "transient," used in the echocardiogram report by the reviewing cardiologist, Dr. Fellows, was "vague." The echocardiogram report, however, stated, "[T]ransient mitral regurgitation and transient to mild aortic insufficiency." It is clear, given that Dr. Fellows described decedent's mitral regurgitation as "transient" and his aortic regurgitation as "transient to mild," that the word "transient" as used by Dr. Fellows indicates something less than mild. Under these circumstances, we find that the Estate has failed to meet its burden of proving that there is a reasonable medical basis for a representation that decedent had at least mild mitral regurgitation based on the December 19, 1997 echocardiogram.

Moreover, we reject the Estate's argument that it may establish the requisite level of mitral regurgitation by reference to decedent's Autopsy Report. As we previously held in PTO No. 7091 at 4 (Apr. 5, 2007), the eligibility language

13. (...continued)
appropriate independent of the auditing cardiologist's finding. For this reason as well, we need not reach claimant's arguments with respect to whether the auditing cardiologist complied with the Audit Rules.

contained in Section IV.B.1. specifically requires that eligibility be established "by an Echocardiogram." The results of an autopsy performed more than 18 months after the echocardiogram submitted in support of a claim cannot provide a reasonable medical basis for representations based on the echocardiogram.

For the foregoing reasons, we conclude that the Estate has not met its burden in proving that there is a reasonable medical basis for its Level V Matrix claim. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claim submitted by Mr. Bonzo's spouse.